

**UNITED STATES DISTRICT  
COURT NORTHERN DISTRICT  
OF OHIO EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION  
*THIS DOCUMENT RELATES TO:*  
TRACK THREE CASES**

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**MDL 2804  
CASE NO. 17-MD-2804  
HON. DAN AARON POLSTER**

**PLAINTIFFS' OPPOSITION TO DEFENDANTS'  
MOTION TO EXCLUDE THE OPINIONS AND  
TESTIMONY OF CRAIG McCANN**

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## INTRODUCTION

Importantly, Defendants do not challenge Dr. McCann's qualifications to testify as an expert in this case. Additionally, Defendants do not challenge Dr. McCann's methodology or contest any of the numbers contained in his reports. Instead, Defendants' motion focuses on Dr. McCann's calculations by challenging the data universe and arguing that his calculations are dependent upon the testimony of another one of Plaintiffs' experts, Carmen Catizone. While these challenges may be a proper subject for cross-examination, they are not a basis to exclude his testimony in total. To the extent that Defendants wish to challenge the weight and credibility of Dr. McCann's opinions, they may do so at trial, during cross-examination.

Dr. McCann's role is limited and straightforward: using his data analysis expertise, he applies certain red-flag metrics (some of which are identified by Mr. Catizone and other of which are found in Defendants' own documents) to the Defendants' dispensing data. Dr. McCann's data analysis is relevant and provides the Court with a reasonable range of the total number of prescriptions that Defendants should have identified and investigated. Defendants offer no serious critique to the computations Dr. McCann made.

The Court should deny Defendants' motion and permit Dr. McCann to testify at trial<sup>1</sup>.

## PLAINTIFFS' PRESCRIPTION TEST GROUP

Dr. McCann applied 43 "flagging" algorithms to the dispensing data produced in this action and reported the results. Each of the 43 algorithms is based on one or more of six broad categories of red flags which can be analyzed based on available data: Doctor Shopping; Pharmacy Shopping; Pattern Prescribing; Excessive Dispensing (*e.g.*, frequency, volume, high doses, days' supply, early refills); Suspicious Combinations (*e.g.*, cocktails, two short-acting opioids dispensed

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<sup>1</sup> The legal standards applicable to *Daubert* motions are set forth in *Plaintiffs' Opposition to Certain Defendants' Daubert Motion to Exclude the Opinions Offered by James Rafalski*, to which the Court is respectfully referred.

together); and Cash Payments.<sup>2</sup> As noted in prior briefing, the Pharmacy Defendants and their trade organization, the National Association of Chain Drug Stores (“NACDS”) recognized these core categories of red flags as early as January 2013. *See* Dkt. #s 3719; 3719-2, and 3719-3. These 43 algorithms consist of the 27 computations set out in Plaintiffs’ June 2020 red flag submission *and* the 16 computations disclosed in both the McCann and Catizone April 2021 expert reports. Many of the originally-run 27 computations, which were narrower, are subsumed within the broader 16 computations in the expert reports.

In accordance with this Court’s Order to identify the universe of prescriptions that they intend to rely on at trial, Plaintiffs elected to rely on a “Test Group” of prescriptions consisting of those prescriptions that were triggered by a *combination* of at least one of the 16 red flag computations disclosed in the April 2021 reports (1 to 16), *and* at least one of the 27 red flag computations disclosed in the June 2020 submission (17 to 43). Each prescription in this Test Group was flagged by both sets of computations. Dr. McCann’s second supplemental report summarizes the 884,166 (the “884K”) prescriptions that were triggered by a combination of those two sets of computations.

## ARGUMENT

### **I. DR. MCCANN’S DISPENSING ANALYSES DO NOT DEPEND ENTIRELY ON THE EXPERT OPINIONS OF CATIZONE AND, TO THE EXTENT THEY DO, THE ANALYSES ARE RELIABLE AND ADMISSIBLE**

Defendants contend that the only way Dr. McCann’s dispensing analyses can assist the trier of fact is if Catizone validates Dr. McCann’s numbers as evidence of improper dispensing by Pharmacy Defendants. Motion at 5. Defendants’ argument ignores the fact that the six categories of red flags (Doctor Shopping, Pharmacy Shopping, Pattern Prescribing, Excessive Dispensing, Suspicious Combinations, and Cash Payments) are widely recognized red flags that Defendants’

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<sup>2</sup> Suspicious patient behavior is also a red flag which may be exhibited through signs of intoxication, use of slang to refer to prescription opioids, etc., however, because these behaviors are not reflected in the data, this is not one of the factors considered by the algorithms.

own trade organization endorsed. Defendants' argument also fails to account for the fact that many of the 43 algorithms are based upon or integrate Defendants' own red flag systems and definitions. As noted in Dr. McCann's report, the flagging criteria he utilized "can be found in or is supported by documents produced by the defendants (including but not limited to defendant's policies, procedures and training materials), DEA guidance and decisions, court decisions, guidance from State Boards of Pharmacy, negotiated consensus documents published by the National Association of the Boards of Pharmacy, and/or by industry trade groups such as the National Association of Chain Drug Stores, medical literature, testimony in *In Re: National Prescription Opiate Litigation*, Case No. 18-md-2804 (MDL), and/or the Expert Report of Carmen Catizone." Dkt. # 3852-10 (Craig McCann Report) at p. 150, n.44.

For example, Suspicious Combination Red Flag computations 5, 6, and 39 relate specifically to the dispensing of a combination of an opioid, a benzodiazepine, and a muscle relaxer. *See* Dkt. # 3719-1. Defendants recognized this combination as a red flag for diversion. For example, Walgreens's RX Integrity department noted that "it is publically [sic] documented that the 'trinity' or 'cocktail' of an opioid, benzodiazepine and a muscle relaxer is a **major red flag** in the eyes of the DEA and NABP."<sup>3</sup> Similarly, Walmart's Policy POM 1311 - Practice Compliance Corresponding Responsibility - Proper Prescriber Patient Relationship lists the following as a Prescription Red Flag "Prescriptions presented represent a 'cocktail' of commonly abused drugs or are presented in a combination that can cause medical complications. (*i.e.* an opioid, a benzodiazepine, and a muscle relaxant) This is often referred to as the 'trinity' or 'holy trinity.'"<sup>4</sup> Rite Aid also recognized the combination of an opioid, a benzodiazepine, and a muscle relaxer as a red flag and instructed its pharmacists to review patient profiles to check for "fills for a combination of products commonly known as the 'trinity' (oxycodone, alprazolam and

<sup>3</sup> *See, e.g.*, Ex. 1 (WAGMDL00037521).

<sup>4</sup> *See, e.g.*, Ex. 2 (WMT\_MDL\_000042987).

carisoprodol or any combination of drugs from these three drug classes).”<sup>5</sup> CVS considered the percentage of oxycodone and hydrocodone prescriptions dispensed to patients who were also filling prescriptions for “either methadone, a benzodiazepine, a muscle relaxant, or a stimulant on the same day.”<sup>6</sup> Giant Eagle also recognized “[p]rescriptions written together for: oxycodone/hydrocodone (opiate) + alprazolam (benzodiazepine) + carisoprodol (muscle relaxant as a potentiator)” as a red flag.<sup>7</sup>

Similarly, Pharmacy Shopping Red Flag computations 4, 22, 23, and 24 relate to prescriptions dispensed at multiple pharmacies. *See* Dkt. # 3719-1. Plaintiffs – and Dr. McCann – need not rely on Catizone’s opinion to treat these as red flags. Defendants themselves recognized that dispensing opioids to patients at multiple pharmacies is a red flag for diversion. For example, Rite Aid’s “High Alert Review Process Overview” identifies “multiple pharmacy locations” as a category requiring more detailed information and due diligence.<sup>8</sup> Walgreens noted that “[p]rescription drug abusers will often attempt to obtain controlled substances from multiple pharmacies during adjacent or overlapping periods of time.”<sup>9</sup>

Pattern Prescribing Red Flag computations 12, 13, 25, 26, 27, and 28 all relate to opioid prescriptions for the same base drug, strength, and dosage form, which were written by the same prescriber. This, too, was a red flag recognized by the Defendants. For example, an internal Walgreens email describes a continuing education course titled “The DEA Opines on Corresponding Responsibility” and notes that the DEA had found that lack of individualization of dosing by the prescribing physician is a red flag.<sup>10</sup> Walgreens 2007 Good Faith Dispensing Policy noted that “[i]ncreased frequency of prescriptions for the same controlled drug by one prescriber”

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<sup>5</sup> *See, e.g.*, Ex. 3 (Rite\_Aid\_OMDL\_0044379).

<sup>6</sup> *See, e.g.*, Ex. 4 (CVS-NYAG-000040732).

<sup>7</sup> *See, e.g.*, Ex. 5 (HBC\_MDL00191292).

<sup>8</sup> *See, e.g.*, Ex. 6 (Rite\_Aid\_OMDL\_0044327).

<sup>9</sup> *See, e.g.*, Ex. 7 (WAGMDL00879313).

<sup>10</sup> *See, e.g.*, Ex. 8 (WAGFLDEA00000467).

should alert a pharmacist to “questionable circumstances.”<sup>11</sup> Walmart considered prescribing the same medication, dosage, and directions for a large number of individuals to be one of several “Prescriber Red Flags.”<sup>12</sup> Rite Aid told its pharmacists that one of the “red flags” that might indicate that a “proper patient-prescriber relationship does not exist” was where the prescriber “writes for the same or similar medications in the same dosage quantities” to most or all of his/her patients.<sup>13</sup> Regardless of any testimony from Mr. Catizone, they are certainly reliable methodologies for showing what Defendants would have seen had they applied the methodologies specified in their own dispensing programs.

To the extent that Dr. McCann does rely on Catizone to identify certain of the red flags in his analyses, moreover, such reliance provides no basis to exclude Dr. McCann’s opinions. For the reasons set forth in Plaintiffs’ opposition to Defendants’ motion to exclude Mr. Catizone’s opinions, Catizone’s opinions are relevant, reliable, and admissible. Dr. McCann is thus permitted to rely on them. *See, e.g., Dura Automotive Systems of Indiana, Inc., v CTS Corporation*, 285 F.3d 609 (7th Cir. 2002); *see also, Ohio Env’tl Dev. Ltd. P’ship v. Envirotest Sys. Corp.*, 478 F. Supp. 2d 963, 976 (N.D. Ohio 2007) (“[A]n expert’s testimony may be formulated by the use of the facts, data and conclusions of other experts.”); *Asad v. Cont’l Airlines, Inc.*, 314 F. Supp. 2d 726, 740–741 (N.D. Ohio 2004) (expert testimony admissible even though based on another expert’s causation opinion)).

Whether based on Defendants’ own acknowledgments about what constitutes a “red flag” or on Catizone’s expert opinions about prescribing red flags, Dr. McCann had an appropriate basis for using the algorithms he did to identify the prescriptions that would have been flagged under each of them. Dr. McCann’s analysis is clearly relevant to establishing the magnitude of Defendants’ wrongful conduct and the harm it caused. Dr. McCann’s data analysis provides an

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<sup>11</sup> *See*, Ex. 9 (WAGMDL00008110).

<sup>12</sup> *See*, Ex. 10 (WMT\_MDL\_000069745).

<sup>13</sup> *See*, Ex. 3 (Rite\_Aid\_OMDL\_0044379).



estimate of the number of red flag prescriptions that Defendants could have identified by using the red flags Defendants themselves identified or, as identified by Mr. Catizone, those they could have or should have used. Dr. McCann's red flag analysis provides an estimate of the magnitude of Defendants' breach of their corresponding responsibility<sup>14</sup> even without any testimony from Mr. Catizone.<sup>15</sup> Dr. McCann's testimony will help the jury understand the scope and breadth of the Defendants' due diligence failures and excessive dispensing.

Defendants seek to minimize Dr. McCann as nothing more than a "human calculator." While it is true that Dr. McCann's methodology is largely arithmetic, it is nevertheless helpful to the trier of fact. Dr. McCann's applications of the various red flag algorithms to the dispensing data are relevant and helpful to resolving issues in this case, including whether Defendants employed reasonable measures to identify potentially suspicious prescriptions and the number of prescriptions Defendants could have reasonably flagged.

**II. DR. MCCANN'S METHODOLOGIES ARE RELIABLE AND RELEVANT, FIT THE FACTS OF AT ISSUE, AND WILL ASSIST THE TRIER OF FACT**

Defendants next object to Dr. McCann's use of Plaintiffs' Test Group of prescriptions, which consists of those prescriptions that were triggered by a *combination* of at least one of the 16 red flag computations (1 to 16) disclosed in the April 2021 reports, *and* at least one of the 27 red flag computations (17 to 43) first disclosed in June 2020. Defendants assert, incorrectly, that this group of 884K prescriptions does not reflect the prescriptions that Catizone says were improper or should have been flagged. Motion at 6. First, as explained above, it is unnecessary for any expert

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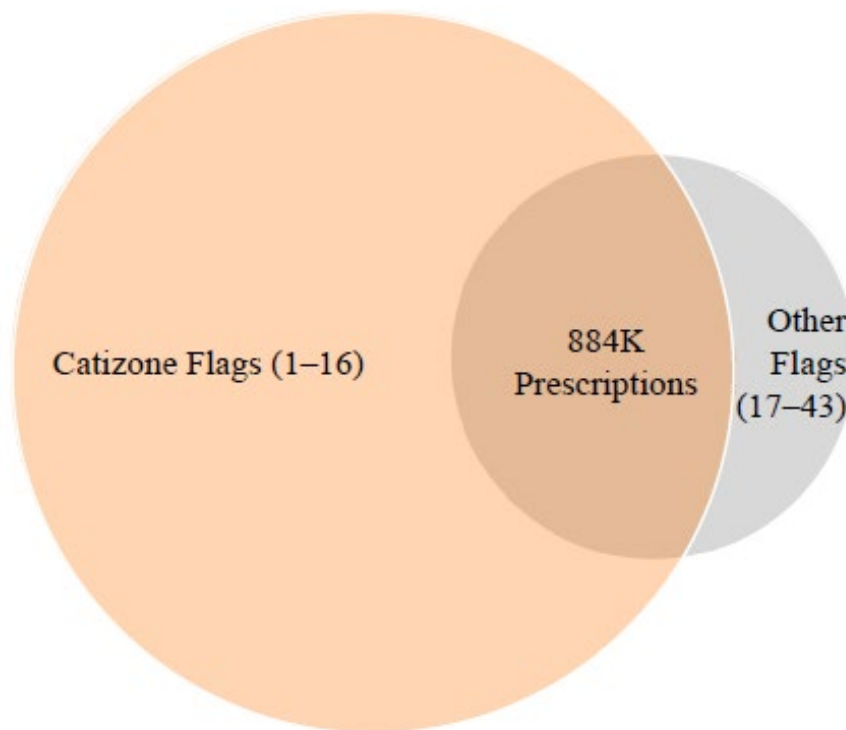
<sup>14</sup> Under the Controlled Substances Act, a pharmacist has a legal responsibility to only dispense controlled substance prescriptions that are written for a legitimate medical purpose in the usual course of professional treatment. This is often referred to as the pharmacist's "corresponding responsibility." According to 21 C.F.R. § 1306.04 (a):

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

<sup>15</sup> Mr. Catizone's opinions are likewise admissible and are addressed in a separate opposition.

to opine that these prescriptions should have been flagged: Defendants' own documents provide that information.

Second, contrary to Defendants' assertion, the Test Group is a subset of the prescriptions discussed in the April Catizone Report. Each of the 884K prescriptions about which Defendants' complain, triggered one of the 16 flags discussed in the April Catizone Report and each was reported in the April McCann Report.<sup>16</sup> For illustrative purposes the subsets that make up the Test Group is shown in the Venn diagram below:



Defendants do not challenge McCann's methodology, i.e., the application of red-flagging algorithms to the dispensing data. Instead, Defendants challenge the universe of red flags reported in the Second Supplemental Report, i.e., the 884 Test Group prescriptions. Defendants conflate the selectivity of the individual prescriptions reported upon with the selectivity of the underlying data and methodology used in applying the red-flagging algorithms to the data. Defendants ignore that Dr. McCann ran the methodology on the *entire universe of prescriptions* and reported the

<sup>16</sup> See, Dkt. # 3859-19 (6/11/21 McCann Tr.) at 116:1-17; 117:2 – 118:25; 134:20 -135:17; 145:24 – 147-2.

results of all 43 red flags in his April report. In his Second Supplemental Report, Dr. McCann identifies those previously identified prescriptions that triggered at least one red flag computation in each of the subsets (computations (1 to 16) and (17 to 43)). There is no new or different methodology, Dr. McCann simply narrowed the previously identified prescriptions to those at issue in the case. Just as a Rule 1006 summary of a subset of data is admissible, so too this subset of previously identified prescriptions is useful and should not be precluded. *See United States v. Hofstetter*, No. 3:15-CR-27-TAV-DCP, 2019 WL 5057176, at \*1 (E.D. Tenn. Oct. 8, 2019) (“summaries of subsets of data are admissible as summaries under Rule 1006.”); see also, *City of Huntington v. AmerisourceBergen Drug Corp.*, No. CV 3:17-01362, 2021 WL 2907893, at \*8 (S.D. W. Va. July 9, 2021) (“Making subsets off limits under Rule 1006 would seriously undermine the purpose of the rule, and the text does not require reading the rule to be self-defeating.”).

Indeed, Dr. McCann is not opining on the appropriateness of the selection; he is simply compiling the list of prescriptions that meet the criteria ordered by the Court.<sup>17</sup> To the extent that Defendants dispute the usefulness of this subset, their challenge is not the expert testimony of Dr. McCann, but to the summary compilation the Court ordered and permitted the Plaintiffs to use.

As the Court is aware, this Test Group of prescriptions is one of the three options this Court proposed regarding which universe of prescriptions Plaintiffs may use at trial. Dkt. # 3726.<sup>18</sup> This Test Group of prescriptions was proposed by the very same Defendants that now object to its use. Dkt. # 3722.<sup>19</sup> It is disingenuous for Defendants to argue on the one hand that the prescriptions

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<sup>17</sup> To the extent that Dr. McCann’s expertise is implicated in identifying this subset, it is his expertise in comparing the results of two sets of algorithms and identifying which prescriptions turn up in both. The “methodology” at issue is standard data analysis and compilation, the reliability of which Defendants do not and cannot challenge.

<sup>18</sup> The Court “proposed three options to Plaintiffs regarding which universe of prescriptions they may use at trial: (1) the original 1 million prescriptions identified in June 2020; (2) the 840,000 overlapping prescriptions; or (3) the 2 million prescriptions identified in April 2021. Dkt. # 3726. Plaintiffs chose option 2 the “overlapping prescriptions” and though Plaintiffs initially estimated the number of overlapping prescriptions to be 840,000, the final tally was 884,166. See Dkt. # 3743.

<sup>19</sup> Complaining about the time needed to analyze the prescriptions identified in the April McCann and Catizone Reports, defendants proposed the following: “If the Court neither grants Defendants’ motion to strike Plaintiffs’

identified in Dr. McCann’s Second Supplemental Report are “inherently arbitrary and unreliable” because they “do not reflect the actual universe” of the prescriptions detailed in the April Catizone Report (Motion at 6) and on the other hand argue Plaintiffs’ should be precluded from referencing “any flagged prescriptions other than the 840,000 overlapping prescriptions” identified by the 16 red flag computations (1 to 16) disclosed in the April 2021 reports, *and* at least one of the 27 red flag computations (17 to 43) first disclosed in June 2020.

Furthermore, any question as to an appropriate universe of prescriptions goes to weight, not admissibility. Data underlying an expert’s opinion does not need to be correct; it need only provide a “reliable foundation” that is something more than “unsupported speculation.” *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517 at 529–30 (6th Cir. 2008) (finding it was not an abuse of discretion for the district court to admit expert testimony where the objection to its admission “fundamentally confuses the *credibility and accuracy* of [the expert's] opinion with its *reliability* . . . . [A] determination that proffered expert testimony is reliable does not indicate, in any way, the correctness or truthfulness of such an opinion.”) (emphasis in original); *See also, In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, 505 F. Supp. 3d 770, 776 (S.D. Ohio 2020) (“Shortcomings of data go to the weight of the evidence, not its admissibility.”). Similarly, arguments about data selection go to the probative value of expert testimony and are not generally grounds for exclusion. *See Marvin Lumber & Cedar Co. v. PPG Indus.*, 401 F.3d 901, 916 (8th Cir. 2005) (complaints that the expert's data was hopelessly flawed “go to the weight to be accorded his opinions by the jury”); *see also Berry v. City of Detroit*, 25 F.3d 1342, 1353 n.11 (6th Cir. 1994) (“Any problem with the selection of [the sample] would have a bearing on the weight to be given the testimony, not its admissibility”). Defendants’ challenges

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untimely red flags (and the million-plus new prescriptions they flag), nor gives Defendants additional time to conduct discovery on this new information, then the Court should at the very least preclude Plaintiffs from referencing at trial any flagged prescriptions other than the 840,000 overlapping prescriptions identified in both Plaintiffs’ June 2020 disclosure and their untimely April 2021 disclosure.” See Dkt. #3722.

to the data set upon which Dr. McCann based his calculations may be a proper subject for cross-examination at trial, but they do not require excluding Dr. McCann's opinion testimony in total.

Defendants criticize Dr. McCann and Plaintiffs for not providing a more focused analysis of individual pharmacies, doctors, patients, or prescriptions. However, as Plaintiffs have repeatedly stated throughout this litigation, Plaintiffs do not intend to prove their nuisance claim against Defendants by arguing that any individual prescription was improperly dispensed.<sup>20</sup> Instead, Plaintiffs will demonstrate that Defendants (i) did not have sufficient policies and procedures in place to identify red flags and (ii) failed to perform appropriate due diligence when red flags were discovered. Dr. McCann has utilized his specialized knowledge and skill to isolate and quantify the prescriptions that should have been red-flagged by Defendants and upon which Defendants should have performed due diligence.

Furthermore, while Dr. McCann's analysis reflects the result of applying the red flag algorithms in the aggregate, Plaintiffs provided Defendants with the Excel files used to generate those charts and tables, just as Plaintiffs did with distribution transactions. These Excel files contain each of the 884K prescriptions in the Test Group as well as columns for each of the red flag tests and indicate whether each prescription would have been flagged by of the 43 red flag computations.<sup>21</sup>

None of the arguments raised by Defendants undercut the reliability and admissibility of the methodology used by Dr. McCann to identify red-flag prescriptions.

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<sup>20</sup> Nor are Plaintiffs seeking damages based on specific prescriptions. Rather, they are seeking abatement of the nuisance caused by Defendants' conduct, an equitable prospective remedy.

<sup>21</sup> Plaintiffs also provided Defendants with Excel files containing the additional prescriptions dispensed by Defendants outside of the Test Group indicating whether each of those prescriptions would have been flagged by one of the 43 red flag computations. *See* Ex. 11, Email serving the May 19, 2021, supplemental expert report and related materials for Craig McCann.

### CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motions to exclude Dr. Craig McCann's opinions and proposed testimony.

Dated: August 18, 2021.

Respectfully submitted,

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